DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 24, 2014

Bard Access Systems, Inc.
Elizabeth U. Peterson
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K133456
Trade/Device Name: Power-Trialysis Short-Term Dialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: August 26, 2014
Received: August 28, 2014

Dear Elizabeth U. Peterson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine and ChloraPrep which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

BARD
ACCESS SYSTEMS

Indications for Use

510(k) Number (if known): K133456

Device Name: Power-Trialysis Short-Term Dialysis Catheter

Indications for Use:

The Power-Trialysis Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Elizabeth U. Peterson Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5472
	Fax Number:	(801) 522-5425
	Date of Preparation:	September 22, 2014
Subject Device	Trade Name:	Power-Trialysis™ Short-Term Dialysis Catheter
	Common Name:	Short-Term Hemodialysis Catheter
	Classification Name:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
	Product Code:	NIE
	Classification Regulation:	21 CFR §876.5540
Predicate Device	Trade Name:	Power-Trialysis™ Short-Term Dialysis Catheter
	Common Name:	Short-Term Hemodialysis Catheter
	Classification Name:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
	Product Code:	NIE
	Classification Regulation:	21 CFR §876.5540
	Premarket Notification:	K083675
	Concurrence Date:	March 19, 2009
Device Description	Power-Trialysis™ Short-Term Dialysis catheters are made of thermosensitive polyurethane, which softens when exposed to body temperature. The catheter is divided into three separate lumens permitting continuous blood flow. Both the venous (blue) and the arterial (red) lumens may be used for hemodialysis, hemoperfusion, and apheresis treatments. The distal (purple) lumen is completely independent from the two dialysis lumens and may be used for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The distal lumen can also be accessed for blood draws and infusion of medications.	

Intended Use / Indications For Use	The Power-Trialysis™ Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.
Technological Characteristics	Vascular access for hemodialysis, hemoperfusion, and apheresis treatments with the additional power injectable third lumen is the technological principle for both the subject and predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements: • Short term use (<30 days). • Insertion technique- Seldinger (over-the-guidewire) or percutaneous procedure into one of the large central veins to place the catheter. • Catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. • Catheter tip placement is in the central venous system with the Superior Vena Cava (SVC) preferred. • Catheter length 12.5 cm, 15 cm, 20 cm, and 24 cm. • The tip configuration of the Power-Trialysis™ is an atraumatic tapered tip. The catheter is skived to create the venous and arterial lumen openings. The power-injectable lumen opening is distal to the venous and arterial lumen openings. The following technological differences exist between the subject and predicate devices: • Addition of side holes for venous and arterial flows • Addition of Alphacurve to catheter shaft tubing • For Alphacurve configurations only: additional catheter markings to indicate effective (insertable) catheter length and suture wing placement. The differences are not critical to the intended use of the device and do not raise any new questions regarding safety or effectiveness.
Safety and Performance Testing	Verification and validation activities were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following performance data were provided in support of the substantial equivalence determination. **Hemolysis** testing was performed by infusing and aspirating blood through the catheters. The evaluation was conducted in accordance with ASTM F1841:1997 (R 2005). **Chemical conditioning** of the catheters before testing for leak, static burst, tensile testing, and shaft to hub tensile testing was performed to ensure the performance of the device was not adversely affected following exposure to chemicals generally used during hemodialysis. Leak testing was conducted in accordance with ISO 10555-1: 1995/Amd 1: 1999/Amd 2: 2004.

Safety and Performance Testing (Continued)	**Occluded Power Injection and Assembly Leak Post Occluded Power Injection** testing were performed to resolve equivalence issues related to the lower static burst threshold of the modified device. **Assembly Burst** testing was performed post power injection to ensure multiple power injection conditioning did not cause the material of the test articles to weaken. **Dialysis Flow** testing was performed to ensure the catheter configurations satisfy established flow rate requirements under labeled dialysis procedural pressures. **Shaft to Hub Tensile** testing was performed to evaluate the integrity of the shaft to hub bond. **Dialysis Lumen Recirculation** testing was performed to determine the percentage of recirculation in forward and reverse flow configurations. **Gravity Flow** testing was performed to determine the flow rate of normal saline through the power injectable lumen. **Catheter Collapse for Dialysis Lumens** testing was performed to ensure the catheter lumens will not collapse at established pressure requirements that could be achieved during hemodialysis procedures. **Catheter Collapse for Power Injectable Lumen** testing was performed to determine the flow rate through the power injectable lumen at a vacuum pressure. **Guidewire Fit** testing was performed to ensure use compatibility between the catheters and guidewires. **Central Venous Pressure Monitoring** testing was performed to verify the capabilities of the catheters in a simulated environment. **Sterilization Validation** was performed to verify the added length of the Power Trialysis Alphacurve Catheter does not adversely impact sterilant residual levels following sterilization. This testing is done in accordance with ISO 10993-7: 2008. The subject device met all predetermined acceptance criteria derived from the above listed testing and demonstrated substantially equivalent performance as compared to the cited predicate device.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Power-Trialysis™ Short-Term Dialysis Catheter meets the requirements that are considered sufficient for its intended use and demonstrates that the subject device is substantially equivalent to the predicate device cited.